

Clarification of a response to a question that was discussed during the first presentation of the Laboratory Quality Series module entitled Proficiency Testing that was offered on November 7, 2008.

Question raise during the session:

Since the regulations state that PT specimens must be treated like patient samples, why do we have clerical staff on the 4 th floor tracking and reminding the Laboratory Supervisors to submit the results by the expected deadline?

Response given during the presentation:

The regulations state that the Laboratory Director is responsible for ensuring that PT results are submitted within the expected turn around time. Failure to meet the reporting deadline is graded as a failure. We have instituted a procedure to ensure that PT specimens are triaged to the proper laboratory and that results are reported within the required turn around time. Our system for handling PT samples has been reviewed during previous inspections and we have not been found to be violating the regulations.

Additional information as a response:

A letter dated September 19, 2008 from CMS was included as a handout for this training session and addresses this question best. Please refer to page 3 of the handout and review the question and answer that appears as the first question on this page. To summarize: After the sample is prepared (pre-analytical phase), PT samples must be treated in the same manner as patient specimens.

Additionally, as stated in the regulations, any time the laboratory must handle a PT specimen differently from how it handles regular patient specimens; the laboratory must document the special handling procedures on the testing worksheet. Examples discussed included the need to reconstitute PT specimens before testing.

This same principle can be applied to the handling of PT specimens during the pre-analytical and post analytical phases. We document the receipt of PT samples and the calls made to obtain results and the date results are faxed. We also have an SOP that documents our process for PT samples that differs from how patient samples are handled.